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Gargiulo v. Isolagen, Inc.  
E.D.Pa., 2007.

Only the Westlaw citation is currently available.

United States District Court, E.D. Pennsylvania.  
Ronald A. GARGIULO individually and on behalf of all other similarly situated, Plaintiffs,  
v.

ISOLAGEN, INC., Frank M. Delape, Robert J. Bitterman, Michael Macaluso, Jeffrey W. Tomz, Olga Marko, William K. Boss, Jr., Michaelavignon, Ralph V. DeMartino, Martin Schmieg, Marshall G. Webb, Stephen Morrell, Henry Y.L. Toh, Citigroup, Inc., Stifel Financial Corp., Legg Mason, Inc., Canaccord, Adams, Inc., UBS Securities, Llc., Legg Mason Wood Walker, Inc., CIBC World Markets Corp., Defendants.

This Document relates to No. 05-04983 and Consolidated Class Actions.

**MDL No. 06-01741.**

Sept. 26, 2007.

[Marc S. Henzel](#), Law Offices of Marc S. Henzel, Bala Cynwyd, PA, [Robert W. Hayes](#), [Cozen O'Connor](#), Philadelphia, PA, for Defendants.

[BUCKWALTER](#), S. J.

\*1 Presently before the Court are Plaintiffs' First Corrected Consolidated Class Action Complaint ("Complaint") (Docket No. 55), Defendant Isolagen and Individual Defendants' Motion to Dismiss (Docket No. 57), Plaintiffs' Response (Docket No. 67), and Defendants' Reply (Docket No. 77). Also, before the Court are the Defendant Underwriters' Motion to Dismiss (Docket No. 49)<sup>[FN1](#)</sup>, Plaintiffs' Response (Docket No. 68), and Defendant Underwriters' Reply (Docket No. 80). For the reasons stated below, Defendant Isolagen and Individual Defendants' Motion to Dismiss is denied.<sup>[FN2](#)</sup> Also, for the reasons stated below, Defendant Underwriters' Motion to Dismiss is denied.

<sup>[FN1](#)</sup> Defendant Underwriters' Motion to Dismiss is found under the multi-district litigation number, MDL No.

06-0174. However, all other docket numbers referenced in this memorandum are found under civil case number, 05-04983.

<sup>[FN2](#)</sup> Individual Defendants refers to:

Officer Defendants: Frank M. DeLape, Michael Malcaluso, Michael Avignon, Robert J. Bitterman, Olga Marko, and Martin E. Schmieg.

Director Defendants: William K. Boss Jr., Steven Morrell, Henry Y.L. Toh, Ralph V. De Martino, Marshall G. Webb, and Jeffrey W. Tomz. Defendant Tomz is represented separately from the above referenced Individual Defendants, but has joined in Isolagen and Individual Defendants' Motion to Dismiss.

### ***I. FACTS AND PROCEDURAL HISTORY***

Plaintiffs are shareholders of Isolagen, Inc. ("Isolagen"), a biotechnology company that engages in the development and commercialization of a cellular therapy for hard and soft tissue regeneration, i.e. a process to counteract wrinkles that relies on a unique technique involving a patient's own collagen-producing cells (the "Isolagen Process"). (Def. Isolagen Mot. Dismiss at 1).<sup>[FN3](#)</sup> Plaintiffs have brought a class action suit on behalf of purchasers of Isolagen's securities during March 3, 2004 to August 9, 2005 (the "class period"). (Compl. ¶ 70.) The Plaintiffs have filed two sets of claims against the collective Defendants. (Compl. ¶ 13.) The first set (Count One through Count Three) alleges fraud-based claims under the Securities Exchange Act of 1934 ("Exchange Act") and is alleged against Defendant Isolagen and Individual Defendants. (Compl. ¶ 13.) The claims, brought under section 10(b) of the Exchange Act, allege that the Defendants used deceptive and manipulative devices in connection with the sale of securities. This set also contains a claim for insider-trading in violation of section 20A of the Exchange Act, as well as a claim for control person liability under section 20 of the Exchange Act. (Compl. ¶ 13.)

[FN3](#). Defendant Isolagen and Individual Defendants Motion to Dismiss will be referred to as Def. Isolagen Mot. Dismiss.

The second set of claims (Count Four through Count Nine) is brought under sections 11 and 12(a)(2) on the Securities Act of 1933 (“Securities Act”) and is asserted against all Defendants. (Compl. ¶ 14.) The claims allege that the registration statements and prospectuses furnished to the public by the Defendants in connection with the publicly issued Isolagen securities contained materially untrue statements and misleading omissions. (Compl. ¶ 14.) Additionally, the second set of claims also asserts control person liability under section 15 of the Securities Act. (Compl. ¶ 14.)

Both sets of claims are based on false and misleading statements in the following general areas: (1) efficacy of the Isolagen Process; [FN4](#) (2) development of the Automated Cellular Expansion (“ACE”) system; [FN5](#) and (3) the filing of the Biologic License Application (“BLA”). [FN6](#) (Pl.’s Opp’n Mot. at 8-9).

[FN4](#). Isolagen Process: a cosmetic treatment in which a patient’s own collagen-producing cells are used to reduce the normal effects of aging on the skin. (Compl. ¶ 80.)

[FN5](#). ACE system: an automated cell growth and harvesting technology. (Compl. ¶ 111; Pl.’s Opp’n Mot. at 3.)

[FN6](#). BLA: a document filed with the United States Food and Drug Administration (the “FDA”) when a company is seeking approval for a biotechnology-derived product. (Compl. ¶ 86.)

Defendant Isolagen and Individual Defendants have filed a Motion to Dismiss the Plaintiffs’ Complaint on the following bases: (1) Defendants’ forward-looking statements are protected by the Private Securities Litigation Reform Act of 1995 (“PSLRA”) safe harbor provision; (2) the Complaint does not allege sufficient facts to establish that Isolagen

made any false statement or give rise to a strong inference of scienter; and (3) all claims asserting control person liability (Counts two, eight, and nine) and insider trading (Count three) must be dismissed for failure to plead a predicate violation. The Court denies Defendant Isolagen and Individual Defendants’ Motion to Dismiss for the reasons below.

\*2 Defendant Underwriters have moved this Court to dismiss the Plaintiffs’ Complaint for the following reasons: (1) the Complaint alleges no actionable misstatements against Defendant Underwriters; (2) Lead Plaintiffs lack standing because they did not purchase securities in the secondary or convertible notes offering; and (3) the claims are barred by the applicable statute of limitations. The Court denies Defendant Underwriters’ Motion to Dismiss for the reasons below.

## II. STANDARD

### A. Motion to Dismiss

A motion to dismiss pursuant to Rule 12(b)(6) is granted where the plaintiff fails to state a claim upon which relief can be granted. [Fed. R. Civ. P. 12\(b\)\(6\)](#). The motion “may be granted only if, accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.” [Maio v. Aetna, Inc.](#), 221 F.3d 472, 482 (3d Cir.2000). While the Court must accept all factual allegations in the complaint as true, it “need not accept as true ‘unsupported conclusions and unwarranted inferences.’” [Doug Grant, Inc. v. Greate Bay Casino Corp.](#), 232 F.3d 173, 183-84 (3d Cir.2000) (citing [City of Pittsburgh v. West Penn Power Co.](#), 147 F.3d 256, 263 n. 13 (3d Cir.1998)). In a [Rule 12\(b\)\(6\)](#) motion, the defendant bears the burden of persuading the Court that no claim has been stated. [Gould Elecs., Inc. v. United States](#), 220 F.3d 169, 178 (3d Cir.2000). Courts generally consider the allegations contained in the complaint, exhibits attached to the complaint, and public records of which the court may take judicial notice. [Pension Benefit Guar. Corp. v. White Consol. Indus.](#), 998 F.2d 1192, 1196 (3d Cir.1993). Although the fact

specific inquiries common to securities cases generally preclude dismissal, courts will nonetheless grant a defendant's 12(b)(6) motion if the alleged misrepresentations or omissions are immaterial or not pled in accordance with Rule 9(b) or PSLRA.

### B. Rule 9(b) and the PSLRA

Because 10(b) and 10b-5 claims involve allegations of fraudulent conduct, courts have long required that they be pled in accordance with Rule 9(b), which provides in pertinent part that "all averments of fraud or mistake shall be stated with particularity." Plaintiffs, through their pleadings, must inject precision and some measure of substantiation into their allegations. *Seville Indus. Machinery Corp. v. Southmost Machinery Corp.*, 742 F.2d 786, 791 (3d Cir.1984). Describing the relevant who, what, when, where and how, such as contained in the first paragraph of any newspaper story, would satisfy the particularity requirement of Rule 9(b). *In re Rockefeller Center Properties Inc., Sec. Litig.*, 311 F.3d 198, 217 (3d Cir.2002).

In 1995, in response to debate over the impact of securities fraud litigation, Congress enacted the PSLRA, which substantially modified, among other things, the standard for pleading securities fraud claims. The PSLRA places additional burdens on plaintiffs attempting to plead fraud in securities cases. Under 15 U.S.C. § 78u-4(b), a plaintiff alleging that a defendant made a misleading statement must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b) (2). Failure to meet the pleading requirements results in dismissal. 15 U.S.C. § 78u-4(b)(3).

\*3 Furthermore, the PSLRA established a safe harbor provision for "forward-looking statements." 15 U.S.C. § 78u-5(c). The term "forward-looking statement" means:

(A) a statement containing a projection of revenues,

income (including income loss), earnings (including earnings loss) per share, capital expenditures, dividends, capital structure, or other financial items; (B) a statement of the plans and objectives of management for future operations, including plans or objectives relating to the products or services of the issuer; (C) a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management or in the results of operations included pursuant to the rules and regulations of the Commission; (D) any statement of the assumptions underlying or relating to any statement described in subparagraph (A), (B), or (C); (E) any report issued by an outside reviewer retained by an issuer, to the extent that the report assesses a forward-looking statement made by the issuer; or (F) a statement containing a projection or estimate of such other items as may be specified by rule or regulation of the Commission.

15 U.S.C. § 78u-5(i)(1). Under the safe harbor provision, Defendants making forward-looking statements are immunized if and to the extent that: (A) the forward-looking statement is (i) identified as a forward-looking statement, and is accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement; or (ii) immaterial; or (B) the plaintiff fails to prove that the forward-looking statement (i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or (ii) if made by a business entity; was (I) made by or with the approval of an executive officer of that entity; and (II) made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.

15 U.S.C. § 78u-5(c)(1).

### III. DISCUSSION

#### A. Defendant Isolagen and Individual Defendants

"To state a securities fraud claim under section

10(b) and rule 10b-5, a private plaintiff must plead the following elements: ‘(1) that the defendant made a misrepresentation or omission of (2) a material (3) fact; (4) that the defendant acted with knowledge or recklessness and (5) that the plaintiff reasonably relied on the misrepresentation or omission and (6) consequently suffered damage.’”[In re Advanta Corp. Sec. Litig.](#), 180 F.3d 525, 537 (3d Cir.1999) (citing [In re Westinghouse Sec. Litig.](#), 90 F.3d 696, 710 (3d Cir.1996)).

As previously stated, Defendant Isolagen and Individual Defendants’ [FN7](#) Motion to Dismiss attacks Plaintiffs’ Complaint on three grounds: (1) Defendants’ forward-looking statements are protected by the PSLRA safe harbor provision; (2) the Complaint does not allege sufficient facts to establish that Isolagen made any false statement or to give rise to a strong inference of scienter; and (3) all claims asserting control person liability (Counts two, eight, and nine) and insider trading (Count three) must be dismissed for failure to plead a predicate violation. The Court denies Defendants’ Motion to Dismiss for the reasons below.

[FN7](#). In Discussion Section A, Defendant Isolagen and Individual Defendants will be referred to collectively as Defendants.

#### (1) Forward-looking Statements:

\*4 Defendants argue that the false and misleading statements and omissions alleged in Plaintiffs’ Complaint are not actionable because they fall within the statutory safe harbor provision that protects forward-looking statements. The Court disagrees. While many of the seventeen statements contain some forward-looking sentences, there are also sentences that contain no forward-looking language and are thus actionable.[FN8](#) [In re Viropharma, Inc. Sec. Litig.](#), No. 02-1627, 2003 WL 1824914, at \*7 (E.D.Pa. Apr.7, 2003) (“Simply because material misrepresentations appear in the same document as a forward-looking statement does not make the statements of fact eligible for the safe harbor.”).

[FN8](#). Examples of Actionable Statements

in the Complaint:

“UK International Registry. The results indicate that 73% of sampled patients tested demonstrated positive results within the first four months after the first injection. All of the patients who were treated with our dermal product showed positive results at six months and one year after first injection....” (Compl. ¶¶ 140, 147; Ex. C at 42; Ex. H at 28.)

“Some of the advantages of our Isolagen Process are as follows: Longer duration of effect.”(Compl. ¶ 145, Ex. B at 4.)

Furthermore, the Plaintiffs, through confidential witness number two (“CW # 2”), have alleged that the Defendants were aware that in the U.K., the results for patients aged 45 and older were ‘appalling,’ according to one prominent London physician [CW# 2] who was among the first doctors to start treating patients using the Isolagen Process and who had, by 2004 treated more than 50 patients.... Indeed, according to CW# 2, for patients aged 45 and older, approximately 80% showed no improvement at all-even after taking multiple injections over the course of a year or more.

(Compl.¶ 92.) Thus, though some of the statements are forward-looking and contain cautionary language, they are still not protected by the PSLRA safe harbor because Plaintiffs allege that Defendants had actual knowledge of falsity. [15 U.S.C. § 78u-5\(c\) \(B\)\(I\)](#) (stating that the safe harbor protection would not apply if the plaintiff proved that there was actual knowledge that the statement was false or misleading). At this stage in the litigation, the Court is mindful that a motion to dismiss “may be granted only if, accepting all well-pleaded allegations in the complaint as true, and viewing them in the light most favorable to plaintiff, plaintiff is not entitled to relief.”[Maio](#), 221 F.3d at 482. As stated above, the Plaintiffs have alleged sufficient facts that if accepted as true, establish knowledge on the part of the Defendants that statements, concerning the efficacy of the Isolagen Process, made in press releases, registration statements, and prospectus filings, were false or misleading or omitted a material

fact. Therefore, those statements are not protected by the PSLRA safe harbor provision and are actionable.

## (2) Scienter:

Under the PSLRA, the scienter element requires that “the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.” 15 U.S.C. § 78u-4(b)(2). “As the PSLRA’s particularity requirement for scienter deviates from Rule 9(b)’s approval of general pleading, the PSLRA ‘supersedes Rule 9(b) as it relates to Rule 10b-5 actions.’” In re Astea Inter. Inc. Sec. Litig., No. 06-1467, 2007 WL 2306586, at \*9 n. 11 (E.D.Pa. Aug. 9, 2007) (citing In re Advanta Corp. Sec. Litig., 180 F.3d at 531 n. 5). In the recent Supreme Court decision, Tellabs, Inc. v. Makor Issues & Rights, LTD., --- U.S. ---, ---, 127 S.Ct. 2499, 2510, 168 L.Ed.2d 179 (2007), the Court determined that “[a] complaint will survive, ..., only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.” Plaintiffs may establish a strong inference of scienter: “either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.” In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1418 (3d Cir.1997) (citing Acito v. IMCERA Group, Inc., 47 F.3d 47, 52 (2d Cir.1995)). The Tellabs decision makes clear the court’s inquiry is “whether *all* of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.” Tellabs, 127 S.Ct. at 2509 (emphasis in the original).

\*5 In the present case, Defendants argue Plaintiffs have failed to state a claim under Rule 10b-5 because Plaintiffs did not allege particularized facts giving rise to a strong inference of scienter. In other words, Defendants argue that the Plaintiffs failed to

plead with particularity facts sufficient to establish that Defendants acted with the intent to defraud the Plaintiffs. However, this Court has determined that the Plaintiffs, by establishing motive and opportunity, have met their burden and pled facts with sufficient particularity to give rise to a strong inference of scienter. Plaintiffs, through two confidential witnesses, U.K. Doctors that administered the Isolagen Process, established that the Isolagen Process was ineffective in their target demographic market (patients aged 45 and older) as well as the fact that there was no standardized injection technique among doctors administering the Isolagen Process. (Compl.¶¶ 92, 94.) Furthermore, Plaintiffs alleged with particularity, through court documents filed in a lawsuit with a company Isolagen contracted with to design the ACE system, that while the Defendants were making public statements about the progress and development of the ACE system, in fact there was not even a preliminary design contract in place for the system. (Compl.¶ 128.) Moreover, the Plaintiffs have alleged with particularity that Defendants had the motive and opportunity to commit fraud in the form of insider sales and corporate securities offerings because Isolagen’s securities prices were artificially inflated due to the above referenced false and misleading information provided to the public, and Individual Defendants sold their respective securities at the time for a considerable gain. (Compl.¶¶ 223, 225.) The Tellabs decision states that, “motive can be a relevant consideration, and personal financial gain may weigh heavily in favor of a scienter inference....” Tellabs, 127 S.Ct. at 2510. It is therefore apparent that at this stage in the pleadings, Plaintiffs have alleged particularized facts sufficient to establish that the Defendants acted with a strong inference of scienter.

## (3) Claims Asserting Control-Person Liability and Insider Trading:

The Defendants argued that claims asserting control-person liability (counts two, eight and nine) and insider trading (count three) should be dismissed for failure to adequately plead a predicate violation. However, in light of the above determina-



tions, which establish a predicate violation, these arguments are now moot.

## **B. Defendant Underwriters**

As previously stated, the Defendant Underwriters have filed a Motion to Dismiss Plaintiffs' Complaint for the following reasons: (1) the Complaint alleges no actionable misstatements; (2) Lead Plaintiffs lack standing because they did not purchase securities in the Secondary or Convertible Notes Offering; and (3) the claims are barred by the applicable statute of limitations.

### **(1) No Actionable Misstatements:**

\*6 Defendant Underwriters first argue that the misstatements in the Secondary Registration Statement concerning the efficacy of the Isolagen Process are conclusory. Next, Defendant Underwriters argue they did not have a duty to disclose misstatements because it was anecdotal product development information. Lastly, Defendant Underwriters argue that they had no actual knowledge that the statements were false and misleading and thus the statements are protected under the PSLRA safe harbor provision.

First, the Plaintiffs alleged misstatements regarding the efficacy of the Isolagen Process are not conclusory as Defendant Underwriters suggest. This Court has determined those statements were adequately supported by the Plaintiffs' Complaint. (*See* Compl. ¶¶ 92, 93, 95.)

Second, Defendant Underwriters argue that they did not have a duty to disclose the misstatements because the misstatements concerned anecdotal, not material, product development information. As a preliminary matter, the Court tends to agree with Plaintiffs that it is not appropriate at this stage in the pleadings to dismiss based on the importance, or lack thereof, of the product development information. As the Third Circuit pointed out in *In re Adams Golf, Inc.*, 381 F.3d 267, 274-275 (3d Cir.2004): "Materiality is ordinarily an issue left to the factfinder and is therefore not typically a matter for Rule 12(b)(6) dismissal." Furthermore, dismissal

on the basis of the materiality of the product development information would only be appropriate "if the alleged misrepresentations or omissions are so obviously unimportant to an investor that reasonable minds cannot differ on the question of materiality...." *Shapiro v. UJB Financial Corp.*, 964 F.2d 272, 281 n. 11 (3d Cir.1992). The product development information is likely relevant to investors and thus, the Court denies Defendant Underwriters' Motion to Dismiss on that basis.

Finally, Defendant Underwriters argue that they had no actual knowledge that the statements were false and misleading and thus, the statements are protected under the PSLRA safe harbor provision. While Defendant Underwriters are correct that actual knowledge of the misstatements has not been alleged against them, the PSLRA safe harbor provision does not afford protection to all the alleged misstatements in the Secondary Registration Statement and Convertible Notes Registration Statement. *In re Viropharma, Inc. Sec. Litig.*, 2003 WL 1824914, at \*7 ("Simply because material misrepresentations appear in the same document as a forward-looking statement does not make the statements of fact eligible for the safe harbor."). In this case, the alleged misstatements are not all forward-looking statements and thus are not all protected by the safe harbor provision. By way of example, "[w]e are in the final stages of developing our new Automated Cell Expansion, or ACE, System." (Compl.¶ 278.) Plaintiffs have alleged that there was not even a design contract in place for the ACE system while the Defendants were publicly announcing its progress and development of the ACE system. (Compl.¶ 128.) Thus, this another example of a statement that is actionable because it is not forward-looking.

\*7 Furthermore, Defendant Underwriters have claimed there are only eight misstatements alleged against them. The Court, however, has determined that there are more sentences contained in the Secondary Registration Statement and Convertible Notes Registration Statement than the eight sentences argued by the Defendant Underwriters. By way of example, "All of the patients who were

treated with our dermal product showed positive results at six months and one year after first injection....” (Compl.¶ 280.) This statement is clearly not forward-looking and thus, not protected by the safe harbor. Rather, this statement conveys to the market the current status of the U.K. clinical trials, and therefore the truth or falsity of this statement was determinable at the time it was made-making this statement actionable. In re Viropharma, Inc. Sec. Litig., 2003 WL 1824914, at \*7 (“A forward looking statement is one whose truth or falsity cannot be determined until after the statement has been made.”)

In conclusion, while some of the misstatements are forward-looking and accompanied by cautionary language thus giving them safe harbor protection, others are not. Therefore, Defendant Underwriters' Motion to Dismiss on the basis that the misstatements are not actionable is denied.

### (2) Standing

Defendant Underwriters argue that Lead Plaintiffs lack standing to file section 11 and section 12(a)(2) claims because Lead Plaintiffs failed to purchase Isolagen shares in the secondary stock offering and/or failed to purchase notes in the convertible notes offering. However, the Court tends to agree with Plaintiffs' “threshold” argument that dismissal based on a lack of standing at the pleading stage is inappropriate. In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d 256, 274 n. 7 (3d Cir.2006) (“The question here is ... a factual one, to be resolved through discovery, as to whether plaintiffs can demonstrate that the shares they allegedly purchased are in fact traceable to the registration statement alleged to be false and misleading.”).

Moreover, the Court has determined that Lead Plaintiffs have adequately pled standing because in their Complaint, Plaintiffs stated that certain plaintiffs and members of the Class purchased Isolagen securities issued in, or traceable to, the offering of Isolagen securities that were conducted pursuant to either the Secondary Registration Statement or the Convertible Notes Registration State-

ment. (Complaint ¶¶ 296, 305, 315, 326). The Court “[f]or the purposes of determining standing, ... must accept as true all material allegations set forth in plaintiffs' complaint and must construe those facts in favor of the plaintiffs.” Mariana v. Fisher, 338 F.3d 189, 205 (3d Cir.2003). Furthermore, the Third Circuit has stated that “[a]t the pleading stage, ... we accept as true plaintiffs' allegations that they made their stock purchases in or traceable to the *Suprema* public offerings.” In re Suprema Specialties, Inc. Sec. Litig., 438 F.3d at 274 n. 7. In accepting this as true there is no doubt that Plaintiffs have adequately pled standing.

\*8 For the above reasons, the Court has determined that Defendant Underwriters' Motion to Dismiss based on lack standing is denied.

### (3) Statute of Limitations

Defendant Underwriters argue that the claims alleged against them by the Plaintiffs are barred by the applicable statute of limitations because (1) Plaintiffs did not affirmatively plead in compliance with section 13's requirements, and (2) Plaintiffs were on inquiry notice of their purported claims for more than one year before suing the Defendant Underwriters.

The applicable statute of limitations for section 11 and 12(a) (2) claims is set forth in section 13 of the Securities Act and provides in relevant part:

No action shall be maintained to enforce any liability created under section 11 or section 12(a)(2) unless brought within one year after the discovery of the untrue statement or the omission, or after such discovery should have been made by the exercise of reasonable diligence ... In no event shall any such action be brought ... more than three years after the security [was offered or sold].

15 U.S.C. § 77m; Benak v. Alliance Capital Management L.P., 349 F.Supp.2d 882, 887 (D.N.J.2004).

The Court has determined that the Plaintiffs have affirmatively pled in compliance with Section 13's requirements. (See Compl. ¶¶ 308, 309, 329.)

Plaintiffs learned of Defendants fraudulent statements in August 2005 and added the Defendant Underwriters as parties to the Complaint in July 2006 within one year of discovery as required by statute. (Def. Underwriters Mot. Dismiss at 1; Pl. Mot. in Oppos'n at 8).

Defendant Underwriters, however, claim that Plaintiffs were put on inquiry notice of their potential claims by three public disclosures. Specifically, the Defendant Underwriters view these three public disclosures as "storm warnings." The Third Circuit has held that "[a] plaintiff in a securities fraud action is put on inquiry notice when a reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning." DeBenedictis v. Merrill Lynch & Co., Inc., 492 F.3d 209, 216 (3d Cir.2007) (internal citations omitted). "Whether the plaintiffs, in the exercise of reasonable diligence, should have known of the basis for their claims depends on whether they had sufficient information of possible wrongdoing to place them on inquiry notice or to excite storm warnings of culpable activity." In re NAHC, Inc. Sec. Litig., 306 F.3d 1314, 1325 (3d Cir.2002) (internal citations omitted). "The test for storm warnings is an objective one, based on whether a reasonable investor of ordinary intelligence would have discovered the information and recognized it as a storm warning." *Id.* "In the context of a motion to dismiss, defendants bear a heavy burden of demonstrating as a matter of law that the plaintiffs had inquiry notice of the alleged violation prior to the plaintiffs filing the complaint." Cal. Pub. Employees' Ret. Sys. v. Chubb Corp., No. 00-4285, 2002 WL 33934282, at \*25 (D.N.J. June 26, 2002).

\*9 The Defendant Underwriters have failed to meet the "heavy burden" of demonstrating that Plaintiffs were on inquiry notice due to the three public disclosures made by the Defendants. Defendants point to the following disclosures as supposed storm warnings:

1. [June 10, 2004 Secondary Registration Statement:] [R]esults did not show a statistically different effect in the treatment and placebo groups using the 5-point scale, designated in the clinical plan as

the primary efficacy assessment. (Def. Underwriters Mot. Dismiss at 22; Ex. G at 27).

2. [June 2004 Secondary Offering Registration Statement:] We expect to file a Biologics License Application for this product candidate during the first quarter of 2005, but on October 20, 2004, Isolagen publicly announced that it would not be filing the BLA in the first quarter of 2005 after all, but instead hoped to do so by the second half of the year. (Def. Underwriters Mot. Dismiss at 23; Ex. L).

3. [September 10, 2004 Investor Conference Call:] [T]he ACE system would not be fully implemented until early 2005. (Def. Underwriters Mot. Dismiss at 24) (quotation omitted).

While the first disclosure may be a storm warning in itself, it is accompanied by reassuring statements which are sufficient to dissipate any storm warning. LC Capital Partners, LP v. Frontier Insurance Group, 318 F.3d 148, 155 (2d Cir.2003) ("There are occasions when, despite the presence of some ominous indicators, investors may not be considered to have been placed on inquiry notice because the warning signs are accompanied by reliable words of comfort from management."). The reassuring statements in this case include:

In contrast, after four months, patients that used the target dosage experienced a statistically significant change using the visual analog scale.

The difference between the results was explained by the failure of the 5-point scale to capture efficacy data from patients whose baseline value was thought to be more severe than five. If the scale had extended to seven then a proportion of patients who showed improvement but did not move to beyond a five would not have been recorded as "responders." In addition, we realized that a two point shift rather than one was needed to separate responders and false responders on this scale. Lastly, if patient's lesions were minor, they were ranked as two at baseline and this did not allow for sufficient sensitivity in the scale to record efficacy.

(Ex. G at 27). The above explains a technical scale which measures the efficacy of the Isolagen Process and more importantly explains why the 5-point scale did not allow for more positive results. Fur-



thermore, “[w]hether reassuring statements justify reasonable reliance that apparent storm warnings have dissipated will depend in large part on how significant the company's disclosed problems are, how likely they are of a recurring nature, and how substantial are the reassuring steps announced to avoid their recurrence.” LC Capital Partners, LP, 318 F.3d at 155. In this case, the reassuring statements concerned an adjustment to the point system for measuring results making it unlikely for the problem to recur and demonstrating that substantial steps were taken to avoid recurrence. Thus, the Court has determined that the first disclosure is insufficient to serve as a storm warning to the Plaintiffs.

\*10 As for the second proposed storm warning, the Court tends to agree with the Plaintiffs assessment that the single line contained in the October 20, 2004 Press Release which stated that “the BLA would be expected to be filed in the second half of 2005” was written not as a negative warning, but as a positive statement. This is evident because the statement preceding it suggested that the time between filing the BLA and commercialization would be reduced by delaying the filing of the BLA. Given the benefits of delaying, the Court has determined that the second disclosure is not a storm warning.

The third and final proposed storm warning concerns the timing of the implementation of the ACE system. The Secondary Registration Statement for 2004 states that the ACE System will be “introduce[d]” in the fourth quarter of 2004, while an investor call said the ACE System would not be “fully implemented” until early 2005. (Ex. C at 26; Def. Underwriters Mot. Dismiss at 24). Clearly this is not a huge discrepancy in time, i.e. fourth quarter 2004 versus early 2005; and thus is insufficient to serve as a storm warning to a reasonable investor. Furthermore, because there is a difference between “introducing” the ACE system and a “fully implemented” ACE System, a reasonable investor is likely to understand that being able to fully implement the ACE system and merely introducing it could and would produce a reasonable delay in

time; and thus not be alerted by a minor delay. Therefore, the third public disclosure does not qualify as a storm warning.

#### IV. CONCLUSION

For the reasons stated above, Defendant Isolagen and Individual Defendants' Motion to Dismiss and Defendant Underwriters' Motion to Dismiss are denied. An appropriate Order follows.

**AND NOW**, this 26th day of September, 2007, upon consideration of Plaintiffs' First Corrected Consolidated Class Action Complaint (Docket No. 55), Defendant Isolagen and Individual Defendants' Motion to Dismiss (Docket No. 57), Plaintiffs' Response (Docket No. 67), and Defendants' Reply (Docket No. 77), it is hereby **ORDERED** that Defendant Isolagen and Individual Defendants' Motion to Dismiss is **DENIED**.

**ALSO**, upon consideration of Defendant Underwriters' Motion to Dismiss (Docket No. 49)<sup>FN9</sup>, Plaintiffs' Response (Docket No. 68), and Defendant Underwriters' Reply (Docket No. 80), it is hereby **ORDERED** that Defendant Underwriters' Motion to Dismiss is **DENIED**.

FN9. Defendant Underwriters' Motion to Dismiss is found under the multi-district litigation number, MDL No. 06-0174. However, all other docket numbers referenced in this order are found under civil case number, 05-04983.

E.D.Pa., 2007.

Gargiulo v. Isolagen, Inc.

Slip Copy, 2007 WL 2791827 (E.D.Pa.)

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